action and until the final determination thereof, from doing any of the following acts, directly or indirectly, in violation of Sections 301 (a) or 301 (k) of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 331 (a) or (k)) with respect to any of the articles of device hereinafter enumerated—namely, the Oscilloclast, Oscillotron, Regular Push Botton Shortwave Oscilloclast, Sweep Oscillotron, Sinusoidal Four-in-One Shortwave Oscillotron, Galvanic Five-in-One Shortwave Oscillotron, Depolaray, Depolatron, Depolaray Chair, Depolatron Chair, Depolaray Junior, Electropad, New Depolaray Junior, and Blood Specimen Carriers—or any similar article of device allegedly capable of transporting blood for diagnosis by the Radioscope or of producing or measuring low power radio waves or electromagnetic energy or low frequency alternating magnetic energy, or any accessory, component, or part of any such article:

"(1) Introducing or causing to be introduced, or delivering or causing to be delivered for introduction into interstate commerce any such article of device which is:

(a) Misbranded within the meaning of Section 502 (a) of the Act (21 U. S. C. 352 (a)) by reason of any representation or suggestion in its labeling which conveys the impression that such article, or any of the other articles enumerated above, including the Radioscope, has value in the treatment or diagnosis of any kind of disease condition or has value in affecting any structure or function of the body of man or other animals; or

(b) Misbranded within the meaning of Section 502 (a) of the Act (21 U. S. C. 352 (a)) by reason of any other false or misleading representation or suggestion in its labeling; or

(c) Misbranded within the meaning of Section 502 (f) (1) of the Act (21 U. S. C. 352 (f) (1)) in that its labeling does not bear adequate directions for use because it does not contain a statement of all the purposes and conditions for which the articles are intended by the defendants; or

(d) Adulterated within the meaning of Section 501 (c) of the Act (21 U. S. C. 351 (c)) in that (1) its strength differs from or its quality falls below that which it purports or is represented to possess, or (2) it purports to produce or measure low power radio waves or electromagnetic energy or low frequency alternating magnetic energy which, when applied to the body, "normalize" disease tissue thereby correcting disease conditions, or (3) it purports to have diagnostic or therapeutic qualities; or

"(2) Doing any act or causing any act to be done with respect to any such article while such article is held for sale after shipment in interstate commerce which results in said article becoming misbranded or adulterated in any of the aforesaid respects; and

"IT IS FURTHER ORDERED that this injunction shall remain in effect until final disposition of this cause by this Court after trial on the merits; and

"IT IS FURTHER ORDERED that any trial on the merits shall be preceded by at least 90 days' notice to all parties with opportunity for utilizing the discovery and pre-trial procedure; and

"IT IS FURTHER ORDERED that at any such trial on the merits defendants' consent to this Decree shall not be deemed an admission against them, provided, however, that this Decree may be the basis for Contempt proceedings for any violation thereof; and

"IT IS FURTHER ORDERED that this Court expressly retain jurisdiction over the subject matter and parties herein in order that it may issue such further Orders and Decrees as may be necessary to the proper disposition of this proceeding."

4668. Voluptae device. (Inj. No. 288.)

COMPLAINT FOR INJUNCTION FILED: 3–11–55, S. Dist. Calif., against Hollywood Models, Inc., doing business under the fictitious name of Voluptae at Los Angeles, Calif., and against Lois Schwartz, also known as Anne Harris, president of the corporation.

CHARGE: The complaint alleged that the defendants were the interstate promoters and distributors of the device designated by the name of *Voluptae*,

which consisted of a large transparent plastic cup with a rubber gasket around the edge and a plastic vacuum pump attached to the cup. In use, the plastic cup was pressed against the chest so that it would enclose one of the breasts and the rubber gasket would form an airtight seal against the chest, after which the plastic pump was manipulated in a manner that created a partial vacuum inside the plastic cup.

The complaint further alleged—

(a) That the defendants were engaged in the interstate sale of the device through two principal techniques, i. e., (1) by a direct mail-order promotion initiated from their principal place of business at Los Angeles, Calif., and (2) by similar promotions initiated by distributors of the device at such cities as Chicago, Ill., Boston, Mass., and Cleveland, Ohio;

(b) That in conducting their direct mail-order promotion of the device from Los Angeles, Calif., the defendants (1) caused newspaper advertisements relating to the device to be printed in cities throughout the United States, (2) utilized extensive mailing lists which included the names and addresses of thousands of women residing in various parts of the United States who would likely be interested in the purchase of drugs and devices represented as effective for breast enlargement, and (3) caused to be mailed to women on such mailing lists certain circulars relating to the device, which circulars were designated as "Voluptae If You're Flat Chested" and "At Last! A Safe . . . New . . . Easy Way That Has Enabled Other Women to Develop a Full Firm Bust!";

(c) That when the defendants received orders for the device in response to the mail-order promotion, they caused the device to be shipped interstate from Los Angeles, Calif., to persons residing in various States throughout the country, and with each such shipment, the defendants enclosed a tie-on tag designated "Voluptae";

(d) That in conducting their sales promotion through distributors, the defendants would furnish the distributors with written, printed, and graphic matter consisting of copies of the above-mentioned advertising, circulars, and tie-on tag, photographs of certain "before and after" pictures of women, as well as copies of testimonial letters, physicians' statements, physicians' prescriptions, and physical therapists' letters; and that from such materials, the distributors would compile a Voluptae Sales Brochure;

(e) That the defendants caused bulk interstate shipments of the device to be made from time to time from Los Angeles, Calif., to such distributors; and

(f) That when the defendants caused the device to be introduced into interstate commerce, the labeling of the device included the above-mentioned circulars and tie-on tags and in some instances the materials used for the compilation of the Voluptae Sales Brochure.

The complaint alleged further that the defendants were violating Section 301 (a) of the Act by causing the introduction and delivery for introduction into interstate commerce of the device which was misbranded; that they were also violating Section 301 (k) of the Act by causing the association of the device with labeling consisting of the above-mentioned circulars, tie-on tags, and sales brochure, while the device was held for sale by the distributors after shipment in interstate commerce, which resulted in the device being misbranded. The device was alleged to be misbranded as follows:

502 (a)—the labeling of the device was false and misleading since it represented and suggested—

(a) That the device was effective for increasing the size of the breasts, for providing shape, growth, and expansion for underdeveloped breasts so that they would become full, round, and firm, and for improving the tone of the breast tissue, whereas the device was not effective for such purposes;

(b) That the device could be used safely without the supervision of a physician, whereas it could not be used safely without the supervision of a physician;

(c) That the directions for the use of the device would assure its safe use without medical supervision, whereas the labeling failed to reveal the material fact that the contraindications suggested in the labeling, including symptoms which were signs of early cancer, could only be detected by a competent physician and that the device should therefore never be used except upon the prescription of a physician;

(d) That physicians and surgeons commonly prescribed the use of the device in the regular course of their practice, whereas physicians and surgeons do not commonly prescribe the use of the device in the regular course of their practice; and

(e) That a number of physicians and surgeons whose letters were quoted in the labeling had approved the device as safe for use by women without the supervision of a physician, whereas such physicians and surgeons had not approved the device as safe for use by women without the supervision of a physician; and

502 (f) (1)—the labeling of the device failed to bear adequate directions for use, and the device was not eligible for an exemption from the requirement that its labeling bear adequate directions for use.

DISPOSITION: On 3–11–55, the court issued a temporary restraining order enjoining the defendants against the commission of the acts complained of. On 4–1–55, the defendants having given notice that they would not contest the case, the court entered a default decree of permanent injunction enjoining the defendants (1) from introducing into interstate commerce the *Voluptae device*, any similar device, or any device or drug offered for similar purposes, which would be misbranded as alleged in the complaint, and (2) from causing the association of labeling with any such device or drug while held for sale by a distributor after shipment in interstate commerce which would result in such device or drug being misbranded as alleged in the complaint.

DRUGS FOR VETERINARY USE

4669. Master Liquid (6 seizure actions). (F. D. C. Nos. 36060/2, 36144/8. S. Nos. 20–447/9 L, 83–856 L, 84–047/50 L.)

QUANTITY: 8 5-gal. cans and 172 1-gal. jugs at Belle Plaine, Carroll, Cherokee, Denison, George, Humbolt, Onawa, and Orange City, Iowa.

SHIPPED: Between 5–19–53 and 9–2–53, from Omaha, Nebr., by Master Laboratories.

LABEL IN PART: "Master Liquid * * * Ingredients: Sodium Thio-Sulphate; Beechwood Creosote; Guaiacol; Powdered Extract of Licorice; Sodium Hydroxide, 9%; Sodium Bicarbonate; Betanapthol; Oil of Anise; Sodium Phenosulfonate; Solution of Potassium Arsenite, (Arsenic as Arsenous Oxide, 0.75%); Nicotinic Acid."